

REMARKS

This Amendment and Reply accompanies the filing of a Request for Continued Examination (RCE) and payment of the required fees, and is being filed within the shortened statutory period set for response. Favorable reconsideration of the subject application is respectfully requested in view of the amendment presented herein and the following remarks. Claims 2-17, 19-21 and 27-35 are pending and under examination, with claim 29 being in independent format.

While applicant does not acquiesce in the outstanding rejections of the (previous) claims, applicant's independent claim 29 is amended for purposes of clarity and to expedite prosecution. Amended independent claim 29 specifies, *inter alia*, that the support layer contacts the overlying layer *substantially continuously* along the length of the free portion. This aspect of applicant's claimed invention is described in the application as filed and as published, for example, at Figs. 1A and 4, and at paragraphs 0027, 0030-0031 and 0052. Applicant submits that this amendment is fully supported in the application as it was originally filed and does not introduce new matter.

Claim rejections under 35 USC §103(a)

The outstanding Office action states that claims 4-7, 11-13 and 32-34 stand rejected under 35 USC §103(a) as being obvious in view of US Patent 5,527,325 to Conley et al. ("Conley et al."). This is a subset of the pending claims and doesn't include independent claim 29. In the detailed rejection, however the Examiner discusses at least claims 29 (paragraph spanning pages 2-3.), claims 2, 3, 4, 5, 6, 7, 12, 13, 21, 27, 28, 31, 32-34 and 35. Applicant therefore treats this as a rejection of all but claims 8-10, 14, 15, 16, 17, 19 and 30, which are expressly rejected on other grounds. Claims 8-10, 14, 15, 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conley et al. as applied to claims 4-19 and 32-35 above, and further in view of Bagaoisan et al., U.S. Patent 6,270,477. These rejections are respectfully traversed.

Claim 29 is the only independent claim pending in this application, and applicant's arguments are directed to the patentability of claim 29. Applicant submits that the Examiner has failed to present a *prima facie* showing of obviousness with respect to claim 29 and that claim 29 and the claims that depend from claim 29 (all of the pending claims) are in condition for allowance.

The Determination of Obviousness

It is well established that the Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988); MPEP § 2142. The determination of obviousness is dependent on the facts of each case. The factual inquiries that form the foundation of any obviousness determination include: (1) the scope and content of the prior art; (2) differences between the claimed invention and the prior art; (3) level of ordinary skill in the art; and (4) secondary indicia of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

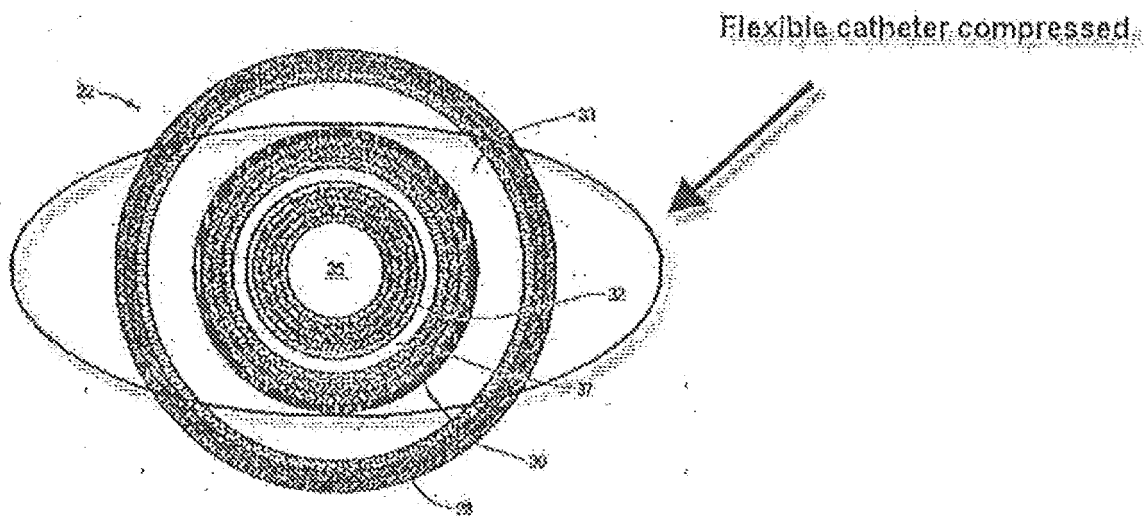
The Supreme Court, in *KSR Intl Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) rejected the teaching-suggestion-motivation (TSM) test as the *sole* test for obviousness and indicated that more flexible, common sense approaches to determining obviousness are also appropriate. Other approaches and obviousness rationales identified by the KSR court are enumerated in the USPTO's KSR Guidelines (2007) and 2010 KSR Guidelines Update. These obviousness rationales essentially pose the question of whether one skilled in the art would be motivated to make a combination of prior art elements in a predictable way that he or she would expect to work for its intended purpose. If so, the invention is obvious; if not, the invention is nonobvious.

It is important to bear in mind that, in determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences *themselves* would have been obvious, but whether *the claimed invention as a whole* would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983); MPEP § 2141.02. If all of the claimed elements are known in the prior art, it may be important to identify what would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR*, 550 U.S. at 398, 82 USPQ2d at 1396. If no such rationale exists, then one cannot conclude that the claim would have been obvious to one of ordinary skill in the art (See, MPEP § 2143).

The prior art relied upon and Applicant's claimed structure

The Examiner asserts that Conley et al. teach an intracorporeal device comprising "an operating head (40); a catheter comprising a tubular structure, the tubular structure comprising:

an overlying layer (28) and a supporting layer (30) defining an internal lumen (37).” The Examiner acknowledges that Conley et al. does not teach that the support layer contacts the overlying layer along the length of the “free portion. The Examiner argues, however, that the device of Conley et al. is fully capable of being configured into the claimed limitation because it is flexible and, by compressing the top and bottom of the flexible catheter, the support layer will (i.e., may be forced to) contact the overlying layer along the length of the free portion while still allowing air through the sides of the flexible catheter. The Examiner’s diagram illustrating this potential configuration is provided below.



In the structure of Conley et al., the element the Examiner identifies as overlying layer (28) is an inflation tube, and the element identified as supporting layer (30) is a housing shaft (See, for example, col. 6, lines 36-47). An annular inflation lumen 33 is positioned between inflation tube 28 and housing shaft 30 for inflating a lateral deflection means, such as a balloon 44. The inflation tube (28) is bonded (indirectly) to housing shaft (30) by means of an intermediate transition tube (34) to preserve the patency of the inflation lumen. (See, Fig. 7 and Col. 9, lines 30-61.)

In contrast, amended independent claim 29 is drawn to an intracorporeal medical device comprising a tubular catheter structure having an overlying layer and a support layer defining an internal lumen, wherein the support layer is attached to the overlying layer at a bonding point and *not* attached to the overlying layer along a free portion, and wherein *the support layer contacts the overlying layer substantially continuously along the length of the free portion,*

whereby the support layer is slippable relative to the overlying layer along the free portion when the tubular structure is bent. There is no annular "space" or "lumen" formed between the support layer and the overlying layer in applicant's claimed structure. As noted in the Amendment and Reply filed on February 3, 2010, the ability of the support layer to slip relative to the overlying layer when the tubular structure is bent surprisingly provides a highly flexible structure with sufficient mechanical integrity and pushability to function as an interventional catheter. Tubular structures having this configuration also reduce the incidence of kinking due to the relative movement of the layers with respect to one another.

Obviousness analysis

The level of skill in the art of interventional catheters and catheter structures is high. The question, for purposes of determining obviousness, is whether one of ordinary skill in the art would be motivated to modify the Conley et al. catheter, which provides an inflation lumen between constituent, coaxially arranged tubular structures, to arrive at applicants' claimed structure, which requires a support layer attached to an overlying layer at a bonding point *and not attached to the overlying layer along a free portion*, wherein the support layer contacts the overlying layer *substantially continuously* along the length of the free portion, and whereby *the support layer is slippable relative to the overlying layer along the free portion when the tubular structure is bent*.

The modification of Conley et al. proposed by the Examiner does not result in applicant's claimed structure.

Conley et al. discloses coaxially arranged tubular structures with an annular inflation lumen provided between the tubular structures. Applicant's claims specify a support layer attached to an overlying layer at a bonding point and *not attached to the overlying layer along a free portion* but, rather, contacting the overlying layer *substantially continuously* along the length of the free portion — i.e., two layers contacting one another substantially continuously along a length with no annular space or lumen between them. Even if one were to accept that one of skill in the art might modify (e.g., squash) the catheter of Conley et al. as proposed by the Examiner, the modified catheter would not meet the requirements of claim 29.

Applicant additionally notes that if the flexible catheter of Conley et al. were modified, or “squashed” to provide the compressed flexible catheter structure proposed by the Examiner by application of local forces or by application of forces along the length of the catheter, the presence of those forces would certainly prevent the support layer from being slippable relative to the overlying layer along the free portion, as specified in applicant’s pending claim 29. Thus, even if it were reasonable to modify Conley et al. to provide areas in which the two layers contacted one another as proposed by the Examiner, this would not result in a catheter structure having a free portion in which the support layer is slippable relative to the overlying layer when the tubular structure is bent.

There is no sound rationale for modifying Conley et al. as proposed by the Examiner

The Examiner has provided no rationale for making the proposed modification to the structure taught by Conley et al. and applicant suggests that none exists. To modify Conley et al. to correspond to the applicant’s claimed structure would eliminate or seriously compromise the functionality of the inflation lumen, which provides an essential function in the Conley et al. device. Applicant submits that one of ordinary skill in the art would *not* be motivated to make this modification to arrive at applicant’s claimed structure, and that the Examiner’s outstanding rejection does not support a *prima facie* showing of obviousness.

Conley et al. teaches against the modification proposed by the Examiner

Rather than providing a rationale for modifying the prior art reference to arrive at applicant’s claimed structure, the Examiner alleges that the device of Conley et al. is “fully capable of being configured” into the claimed invention. This capability is provided by “squashing” the tubular structure of Conley et al. so that the outer tubular structure contacts the inner tubular structure at two points (or, along the length, at two lines). This modification would partially occlude the infusion lumen in two areas, but enlarge the infusion lumen in adjacent areas. While collapse of the outer tubular structure toward the inner tubular structure may tend to occur as a catheter is being navigated to and from an interventional site in highly tortuous vessels, it is highly undesirable and catheters are often reinforced to prevent this type of collapse from occurring. In fact, Conley et al. specifically teach that inflation tube 28, the outer tube forming the exterior portion of the inflation lumen, incorporates braided reinforcement, which

adds hoop strength *to resist crushing*. (See, Col. 1, lines 60-67.) Crushing or deformation of the outer tubular structure of Conley et al., which forms the infusion lumen, is highly undesirable and applicant submits that one of ordinary skill in the art would *not* encourage or adopt the modification of Conley et al. as suggested by the Examiner. In fact, one of ordinary skill in the art would actively work to prevent crushing or deformation of the outer structure forming an infusion lumen, as taught by Conley et al.

Applicant submits that Conley et al. do *not* teach or suggest the subject matter recited in pending independent claim 29, and that the rejection of claims 2-7, 11-13, 21 and 27-35 under 35 USC §103(a) must be withdrawn.

Claim 30 stands rejected under 35 U.S.C. 102(b) as being anticipated by or alternatively, as being obvious over, Conley et al. This rejection is respectfully traversed.

The Examiner asserts that claim 30 is a product-by-process claim. Applicant respectfully disagrees. In particular, applicant notes that claim 30 is drawn to the device of claim 29 “wherein the support layer is welded to the operating head,” not to the device of claim 29 made by a particular process.

The teachings of Conley et al. as they relate to independent claim 29 are discussed above. Claim 30 depends from, and thereby includes all the limitations of, claim 29. It is submitted that, for at least the reasons discussed above with respect to claim 29, Conley et al. do not teach or suggest the subject matter of claim 30 and that this rejection of claim 30 can be properly withdrawn.

Claims 8-10, 14-17 and 19 stand rejected under 35 USC §103(a) as being unpatentable over Conley et al. in view of US Patent 6,270,477 to Bagaoisan et al. (“Bagaoisan et al.”). Claims 8-10, 14-17 and 19 all depend, either directly or indirectly, from independent claim 29. The teachings of Conley et al. as they relate to claim 29 are discussed above.

The disclosure of Bagaoisan et al. relates to catheters for use in emboli containment systems. The Examiner states that Bagaoisan et al. teach the use of a braided wire or coil having gaps to reinforce a tubular body, and asserts that it would have been obvious to modify the device of Conley et al. in view of Bagaoisan et al. “to use a coiled wire as opposed to a braided wire”. Bagaoisan et al. do not overcome the deficiencies of Conley et al. discussed above.

Applicant submits that neither Conley et al. nor Bagaoisan et al., taken either singly or in combination, would have rendered the presently claimed invention obvious to one of skill in the art at the time the invention was made, and that the rejection of claims 8-10, 14-17 and 19 under 35 USC §103(a) must therefore be withdrawn.

Applicant submits that the claimed invention as a whole, as set out in applicants' independent claim 29 and the claims dependent thereon, is not described, or suggested, by Conley et al., or in any combination of Conley et al., with Bagaoisan et al. . Applicants submit that the pending independent claims meet the requirements of patentability and that, consequently, all of the pending claims are patentable.

Concluding Remarks

Every effort has been made to put the subject application in condition for allowance. Should the Examiner have any remaining concerns regarding this application, he is respectfully requested to telephone the undersigned at 206.382.1191.

Respectfully submitted,

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